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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,431	12/06/2001	Shinji Kondo	216109US2X	8204

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/06/2003

1

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,431

Applicant(s)

KONDO ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 and 36 is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other.

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Applicant's election with traverse of Species I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that no reasons for given to support the restriction requirement. This is not found persuasive because the examiner did not make a restriction requirement, but rather an election of species. As such, the evidence in support of the requirement is different and the examiner met his burden. It has been determined by the examiner, however, that the species are not patentably distinct, as will be demonstrated below. Accordingly, the requirement is hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the specification, applicant recites in columns 7-8 that the maximum pressure is the pressure during inflation of the cuff, when the signal from the optical sensor stops fluctuating (see column 7, line 15). It then states that cuff is inflated to a predetermine pressure, and deflated. The point where the optical signal begins fluctuating again is determined to be the minimum pressure. This is not understood, as the pressure where fluctuations stop during inflation and the pressure where the fluctuations start during deflation are inherently the same pressure. It is therefore unclear how the maximum and minimum pressures are the same pressure.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 22, and 35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 22 are rejected in that there is no antecedent basis for the stroke. IN other words, the pressures are measured for each stroke of what? Claim 35 is rejected in that it is unclear under claim 18 says determining the pulse wave, while claim 35 says it is not determined. This appears to be contradictory.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-5, 11, 18, 20-22, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Masuda et al. Masuda et al shows a blood pressure measuring

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system including a photoelectric sensor for measuring the pulse wave having a light emitting and receiving portions 44a, 44b, and 46, a blood pressure meter, and a control portion 29 that receives the output of the photoelectric sensor and determines the volumetric pulse wave, which is a signal that changes with the change in volume of the blood vessels. The blood pressure meter determines both systolic and diastolic pressure based on the photoelectric sensor output, for each stroke of the heart when the device is in monitor mode. The system of Masuda et al also calculates the heart rate. The reference shows both the system and method of using the system.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Tochikubo et al. Masuda et al detects the volume pulse wave. Tochikubo et al further detects pulse wave based on arterial displacement. Hence, it would have been obvious to modify Masuda et al to measure the pulse wave through arterial displacement, as it is merely the substitution of one known measurement method for another.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Bryars et al. Masuda et al does not teach the structure of the pulse wave sensor in as much as it does not show how it attaches to the body. Bryars et al further

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shows the recited structure of an optical pulse sensor. Hence, it would have been obvious to modify Masuda et al to use the structure of Bryars, as it is merely the substitution of one known equivalent sensor for another.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Bryars, as applied to claim 7 above, further in view of Ota et al. Ota et al further teaches that the blood pressure measurement like that of the above combination must be compensated for the angle of inclination of the arm relative to the heart. Hence, it would have been obvious to modify the above combination to perform such a compensation, so as to increase the accuracy of the readings.

Claims 9, 10, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Mathews. Masuda does not compensate for body motion. Mathews uses a second optical sensor to measure noise due to body movement and subtract the signal from the measurement signal to provide a signal free from the effects of noise. Hence, it would have been obvious to modify Masuda et al to provide such a noise correction, to improve the accuracy of the readings. With respect to claims 10 and 26, the examiner takes official notice that it would have been obvious to provide a filter for the noise signal, to eliminate artifacts at a frequency obviously not due to body motion.

Claims 12 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Heinemann et al. Masuda et al does not teach adjusting the intensity of the light source. However, Heinemann et al teaches that such an adjustment is desirable to keep the detector output intensity constant over the

measurement range. Hence, it would have been obvious to modify Masuda et al to use such an intensity adjustment, to provide continuity of measurement from one to the next.

Claims 13 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Clark et al. Clark et al further teaches that it is known in optical systems to provide automatic gain control to keep the measurement signals within the operating range of the system. Hence, it would have been obvious to modify the above combination to provide such gain control, to avoid errors in measurement.

Claims 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Yokozeki. Yokozeki et al shows a combined blood pressure meter blood-amount measuring device. Hence, it would have been obvious to modify Masuda et al to include a blood amount measuring device, to provide the clinician with a more complete picture of the patient's condition.

Claims 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al in view of Masuda et al. Nomura et al shows a system to measure depth of anesthesia from the pulse wave. It would have been obvious to modify Nomura to use the optical pulse wave measuring device of Masuda et al, as it is merely the substitution of on known equivalent pulse wave sensing device for another.

Claims 16, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Hosaka et al. Masuda measures propagation time between an ecg device and a photoelectric sensor. Hosaka teaches that a second optical detector may be substituted for the ecg device in measuring propagation time.

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Hence, there would be two photoelectric sensors. Hence, it would have been obvious to modify Masuda to use a second optical sensor, as it is merely the substitution of one known sensor for another. Hosaka further teaches that propagation time is an indicator of coronary artery disease (arteriosclerosis). Hence, it would have been obvious to modify Masuda et al to provide such an artery disease indication, to provide the clinician with a more complete picture of the patient's condition.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Ota et al. Ota et al further teaches that the blood pressure measurement like that of Masuda must be compensated for the angle of inclination of the arm relative to the heart. Hence, it would have been obvious to modify Masuda to perform such a compensation, so as to increase the accuracy of the readings.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al in view of Hersh et al. In column 4, lines 31-41, Hersh et al teaches that in general in the medical field, if a signal is unobtainable due to artifact, an average of previous signals may be used in its place. It would have been obvious to modify Masuda to use this technique, to increase the accuracy of readings.

Claims 18 and 36 are allowable. Claims 18 and 36 define over the art in that none of the heart determines the pulse wave by optically monitoring movement of the heart itself, as opposed to blood vessels.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the

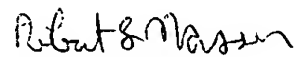
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base claim and any intervening claims. Claim 34 defines over the art of record in that none of the art also determines all three parameters, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
November 3, 2003

**ROBERT L. NASSER
PRIMARY EXAMINER**